REMARKS/ARGUMENTS

Claim 1 has been revised to include the feature of Claim 7, which has been canceled accordingly. All other independent claims, and claims that depend therefrom, have been canceled without prejudice for re-presentation in a continuing application.

Because Claim 1 has been revised to include the feature of previous Claim 7, no new issue for search or consideration has been presented. No new matter has been introduced, and entry of the above revised claims is respectfully requested.

Support for previous Claim 7 and above-revised Claim 1

The Office has indicated that support for previous Claim 7 (and so now revised Claim 1) was not adequately presented. Applicant respectfully points to at least paragraphs [0018], [0025], and [0034] of the instant application (published as US 20070166316 A1) as supporting the concept of an infectious virus particle, produced according to the instant invention, that is inactivated to be non-infectious.

For the convenience of the Office, the first of these three paragraphs ([0018]) is reproduced from page 9 of the original application papers as follows:

> In all aspects of the invention the particle released from the host cells generating the biological particles/carriers is non-infectious. In one embodiment the biological particles/carriers production could be innate to or induced by the introduction into the host cell of viral or non-viral components by mechanical, chemical, and/or viral vector means. In another embodiment the biological particles/carriers production from the host cell could be due to the expression of one or more viral matrix proteins, for example, but not limited to, HIV-1 *gag* protein or the M1 matrix protein of the Influenza virus. In still another embodiment the biological particles/carriers released from the host cell could be an infectious viral particle that is later inactivated by various chemical means including, but not limited to nucleic acid crosslinking inactivation. In all embodiments the released particles could be harvested; concentrated by various methods, including, but not limited to polyethylene glycol; and lyophilized for long-term storage prior to therapeutic use *in vivo*.

As stated in lines 7-9 of the above-quoted paragraph, "biological particles/carriers released from the host cell could be an infectious viral particle that is later inactivated...."

Alleged rejections under 35 U.S.C. § 103

Claims 1-5, 8, 16-20, and 23-26 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Hiserodt et al. (USP 6,277,368) and Wagner et al. (Intervirology, 39(1):93-103, 1996). Applicant has carefully reviewed the statement of the instant rejection as well as the cited documents and respectfully traverses because no *prima facie* case of obviousness is present.

As an initial matter, Applicant points out that independent Claims 8 and 19 have been canceled without prejudice for re-presentation in a continuing application.

With respect to independent Claim 1, Applicant respectfully points out that the claimed subject matter does NOT feature a virus-like particle (VLP) like that allegedly reported by Wagner et al. Instead, the claim features a virus particle that was infectious when produced from a host cell. This feature is not taught, suggested, or otherwise indicated in the cited documents, whether each is taken alone or in combination.

Additionally, Applicant points out that art-recognized differences between virus particles as featured in the claims and virus-like particles (VLPs) were known to the skilled person at the time of the invention. For example, the attached document by Boisgerault et al. (Expert Rev. Vaccines 1(1):101-109, 2002) clearly discuss "killed viruses" and "virions" as distinct from "non-infectious virus-like particles (VLPs) in the first two paragraphs on page 101 after the abstract. More specifically, VLPs are stated as be assembled from structural proteins from viruses and as closely resembling virions. But importantly, VLPS are known as NOT "having the infectious and replicative capacities of the related virus...."

In light of the above-demonstrated knowledge in the art, it is not possible for a VLP to be produced in an infectious form.

The above also responds to the allegations in the Office Action on pages 5-6. In particular, Applicant strenuously disagrees with the assertion bridging pages 5-6 because the legal standard does not support the statement that "the ordinary skilled artisan would understand a virus particle to be a particle from a virus ... given it's ordinary plain meaning and in the absence of any enlightenment by way of the specification." Instead, guidance toward the appropriate legal standard is set forth at MPEP 2111.01 and by the case decisions cited therein. For example, MPEP 2111.01 I. indicates that "plain meaning" cannot be used where such meaning is inconsistent with the specification. As indicated by the paragraph [0018] of the instant application (published as US 20070166316 A1) quoted above, "an infectious viral particle" is expressly disclosed as within the scope of the invention. So any assertion of all non-infectious virus particles as being the same as a VLP is clearly inconsistent with the specification.

Additionally, the instant application refers to "virus particle" and "virus-like particle" *in the alternative* at least on page 9, last paragraph, lines 4-7, and page 14, lines 3-4. So it is inconsistent with the specification to interpret the two terms as having identical meaning or scope.

Additionally, MPEP 2111.01 III. expressly indicates that "plain meaning" refers to the ordinary and customary meaning given to a term by those of ordinary skill in the art. There is simply no evidence of record to support the Office's assertion that "the ordinary skilled artisan would understand a virus particle to be a particle from a virus...." Instead, and as Applicant has previously presented, a virus particle may be infectious or non-infectious while a VLP is always non-infectious. This is consistent with paragraph [0018] as discussed above.

In light of the foregoing, it is not possible for the cited documents to lead to an infectious virus particle that is inactivated as featured in the pending claims. So this rejection may be properly withdrawn.

Claims 1, 19, 21 and 22 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Nawrocki et al. (Cancer Treatment Reviews, 25:29-46, 1999) and Wagner et al. (Intervirology, 39(1):93-103, 1996). Applicant has carefully reviewed the statement of the

instant rejection as well as the cited documents and respectfully traverses because no *prima facie* case of obviousness is present.

As an initial matter, Applicant points out that independent Claims 8 and 19 have been canceled without prejudice for re-presentation in a continuing application. And for the reasons explained above, the two cited documents do not disclose producing a virus particle according to the pending claims, regardless of whether the documents are each taken alone or in combination.

Applicant again points out that the claimed subject matter does NOT feature a virus-like particle (VLP) like that allegedly reported by Wagner et al. Instead, the claim features a virus particle that was infectious when produced from a host cell. This feature is not taught, suggested, or otherwise indicated in the cited documents, whether each is taken alone or in combination.

In light of the foregoing, it is not possible for the cited documents to lead to an infectious virus particle that is inactivated as featured in the pending claims. So this rejection may be properly withdrawn.

Alleged rejection under 35 U.S.C. § 112, first paragraph

Claim 7 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicant has carefully reviewed the statement of the instant rejection and respectfully traverses because no *prima facie* case of "new matter" is present.

Applicant respectfully points out that support for the features of previous Claim 7, which have now been incorporated into Claim 1, is provided at multiple locations in the specification as filed. See for example paragraphs [0018], [0025], and [0034] of the instant application (published as US 20070166316 A1) as explained above.

Additionally, Applicant points out that prior to the response filed October 19, 2009, Claim 7 recited

"The process of claim 1 wherein said non-infectious particle is an inactivated intact virus particle."

Applicant respectfully points out that a skilled person would understand the above claim language to mean that a virus particle had to be "inactivated " in order to produce the featured "non-infectious virus particle" in Claim 7 (as well as Claim 1). Logically, this means that the virus particle must have been infectious at the time of "inactivation". The statement of the instant rejection provides no rationale or evidence as to why a skilled person would not logically understand the claim in this manner.

In light of the foregoing, Applicant respectfully points out that no issue of "new matter" is present, and this rejection may be properly withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned.

Respectfully submitted,

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